Interview Summary	Application No.	Applicant(s)	
	10/505,138	DIETRICH ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Eric E. Silverman, PhD*.

(2) *Michael Woodward*.

(3) *Sheldon McGhee*.

(4) *Joshua Goldberg*.

Date of Interview: *25 July 2006*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *See attached*.

Claim(s) discussed: *as of record*.

Identification of prior art discussed: *as of record*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Applicants presented data showing increased dissolution of rolflumilast in formulations comprising PVP. Applicants will sumbit arguments that the Rennard reference is an invitation to experiment to find what types of PVP are useful to provide these advantageous properties, whereas the current invention has shown specifically which PVP's give advantageous results*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

EXAMINER

Roflumilast Formula B und Formula C: Zusammenfassung für die US-Patenteinreichung; Patent Nr. B1029

Ziel: Für die US-Patenteinreichung von Patent Nr. B1029: Belegung einer langsameren Freisetzung von Formula C gegenüber Formula B Tabletten verschiedener Dosierungen

Formula B Tabletten bestehen aus:	Formula C Tabletten bestehen aus:
• Roflumilast mikronisiert (Wirkstoff) • Lactose – Monohydrat, fein gemahlen (Füllstoff) • Maisstärke (Füllstoff) • Polyvidon K90 (Bindemittel) • Magnesiumstearat, pflanzlich (Schmiermittel)	• Roflumilast mikronisiert (Wirkstoff) • Lactose – Monohydrat, fein gemahlen (Füllstoff) • Maisstärke* (Bindemittel) • Kartoffelstärke (Füllstoff) • Natriumcarboxymethylstärke (Sprengmittel) • Magnesiumstearat, pflanzlich (Schmiermittel) *wird in Form eines Maisstärkekleisters eingesetzt

Zusammensetzungen der einzelnen Dosierungen:

Formula B

Dosierungen	***50 µg***	***125 µg***	***250 µg***	***500 µg***	***1000 µg***	***2500 µg***	
Chargenbezichnungen	***NSy 51/g***	***NSy 51/k****	***NSy 51/m****	***NSy 51/n****	***NSy 51/h***	***NSy 51/i***	
Rezepturbestandteile							
Roflumilast, mikronisiert	0,050	0,125	0,250	0,500	1,000	2,500	mg
Lactose-Monohydrat, fein gemahlen	49,660	49,660	49,660	49,660	49,660	49,660	mg
Maisstärke	13,390	13,390	13,390	13,390	13,390	13,390	mg
Polyvidon K90	1,300	1,300	1,300	1,300	1,300	1,300	mg
Magnesiumstearat, pflanzlich	0,650	0,650	0,650	0,650	0,650	0,650	mg
Summe	*65,050*	*65,125*	*65,250*	*65,500*	*66,000*	*67,500*	mg

*** hergestellt von Altana Pharma Oranienburg**

Formula C

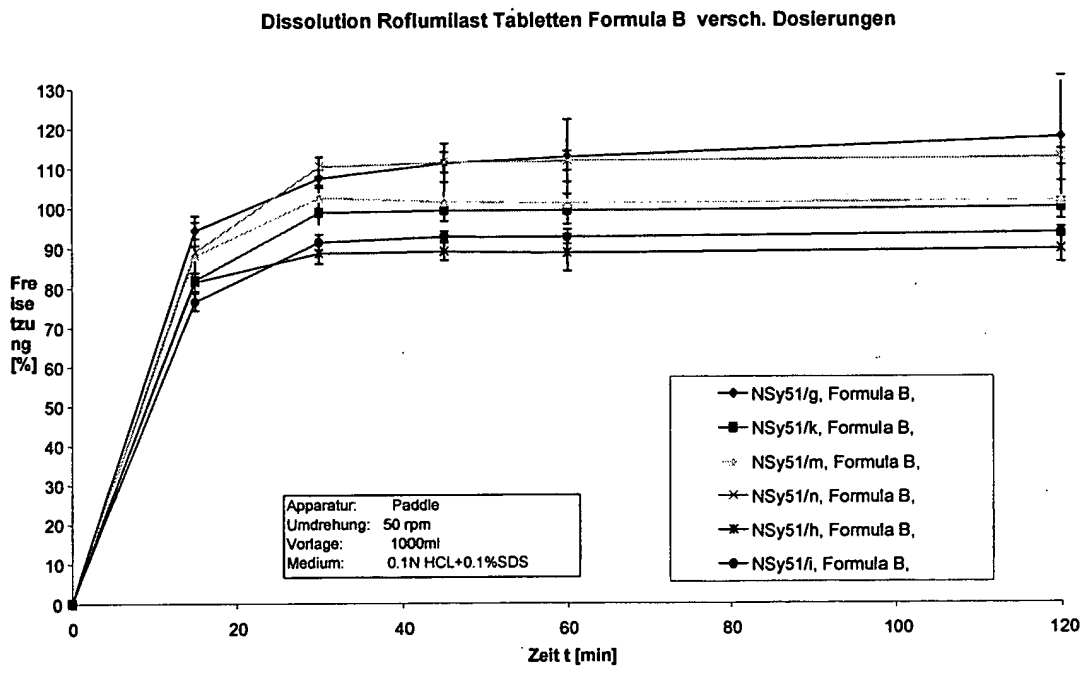
Dosierungen	***50 µg***	***125 µg***	***250 µg***	***500 µg***	***1000 µg***	***2500 µg***	
Chargenbezichnungen	***NSy 51/a***	***NSy 51/b***	***NSy 51/c***	***NSy 51/d***	***NSy 51/e***	***NSy 51/f***	
Rezepturbestandteile							
Roflumilast, mikronisiert	0,050	0,125	0,250	0,500	1,000	2,500	mg
Lactose-Monohydrat, fein gemahlen	70,300	70,300	70,300	70,300	70,300	70,300	mg
Kartoffelstärke	19,475	19,475	19,475	19,475	19,475	19,475	mg
Maisstärke	2,375	2,375	2,375	2,375	2,375	2,375	mg
Natriumcarboxymethylstärke, Primojel	1,900	1,900	1,900	1,900	1,900	1,900	mg
Magnesiumstearat, pflanzlich	0,950	0,950	0,950	0,950	0,950	0,950	mg
Summe	*95,050*	*95,125*	*95,250*	*95,500*	*96,000*	*97,500*	mg

Freisetzungsparameter:

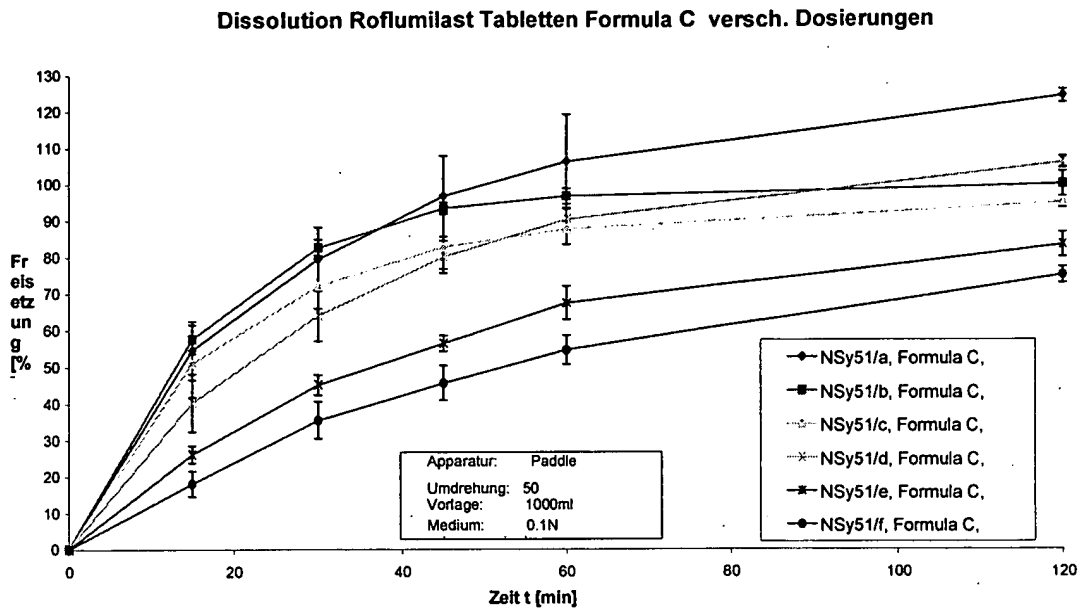
Apparatur:	Paddle
Umdrehung:	50 rpm
Vorlage:	1000 ml (500 ml bei 50 µg)
Medium:	0.1N HCL + 0.1%SDS

Freisetzungsgraphiken:

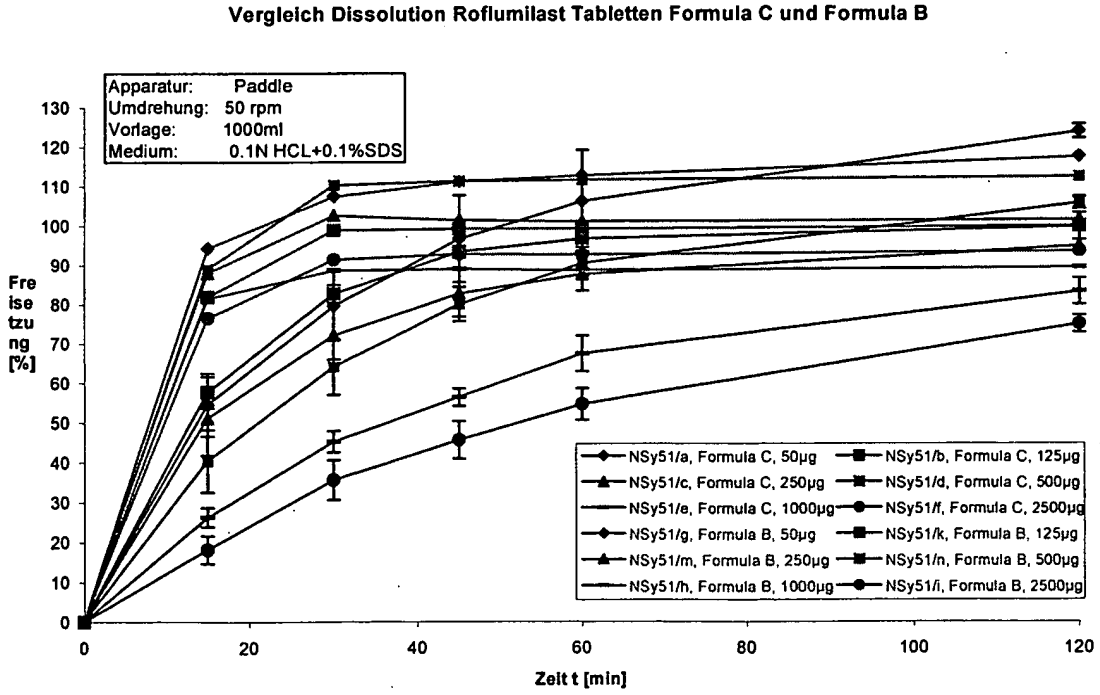
Formula B Tabletten



Formula C Tabletten



Vergleich von Formula B zu Formula C Tabletten

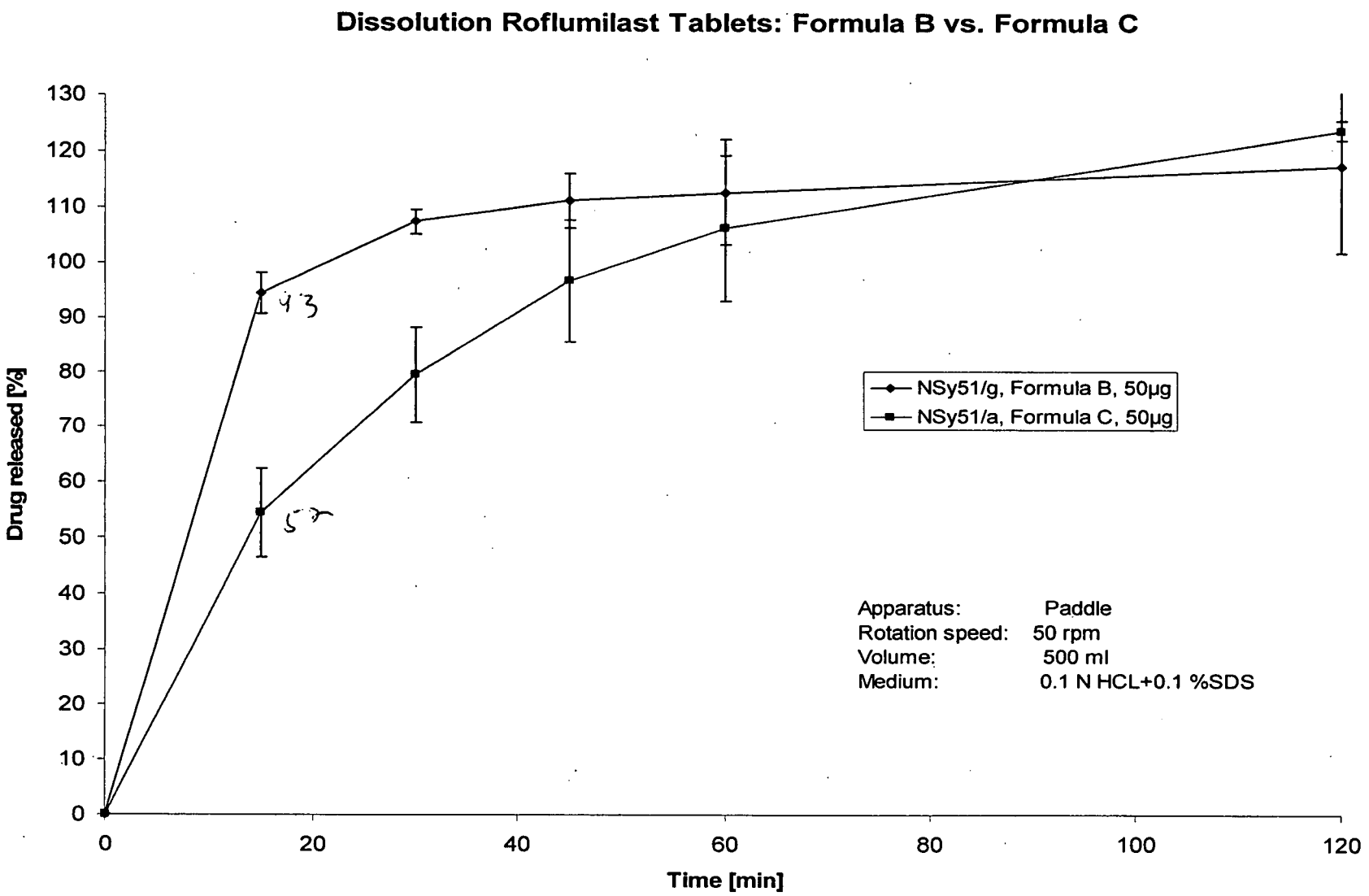


Dissolution method

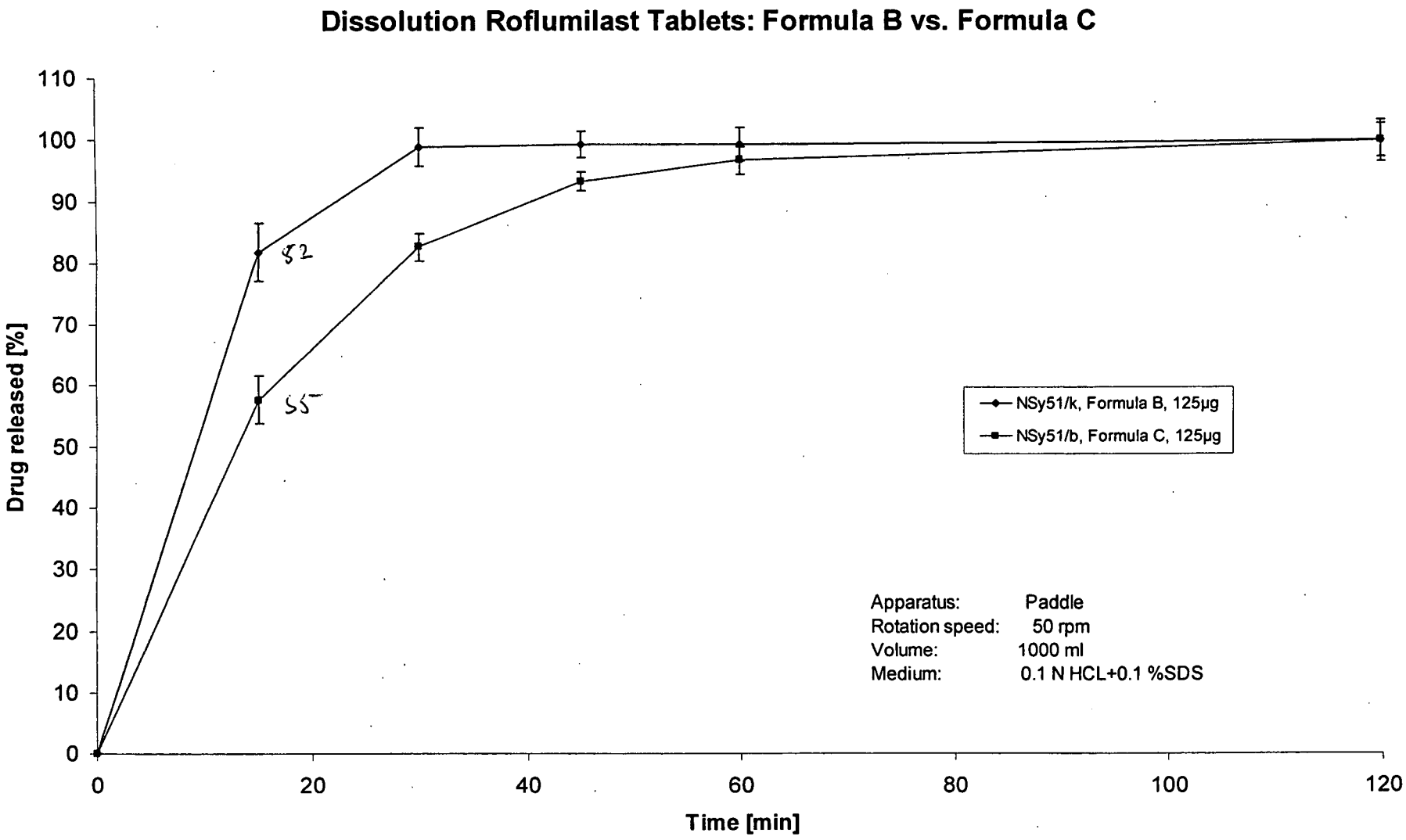
- The dissolution apparatus, apparatus 2 (paddle), was operated in accordance to the requirements of Ph.Eur. 5 and USP 29.
- The chemical analysis of the drug dissolved at each sampling point was performed by HPLC due to the low UV activity of the drug substance.
- The dissolution parameters are shown in the following table:

Apparatus	Apparatus 2 (Paddle)
Medium	0.1 N HCl
Volume	1000 ml (50 µg Roflumilast: 500 ml)
Agitation	50 rpm
Temperature	37 °C
Samples	n = 6

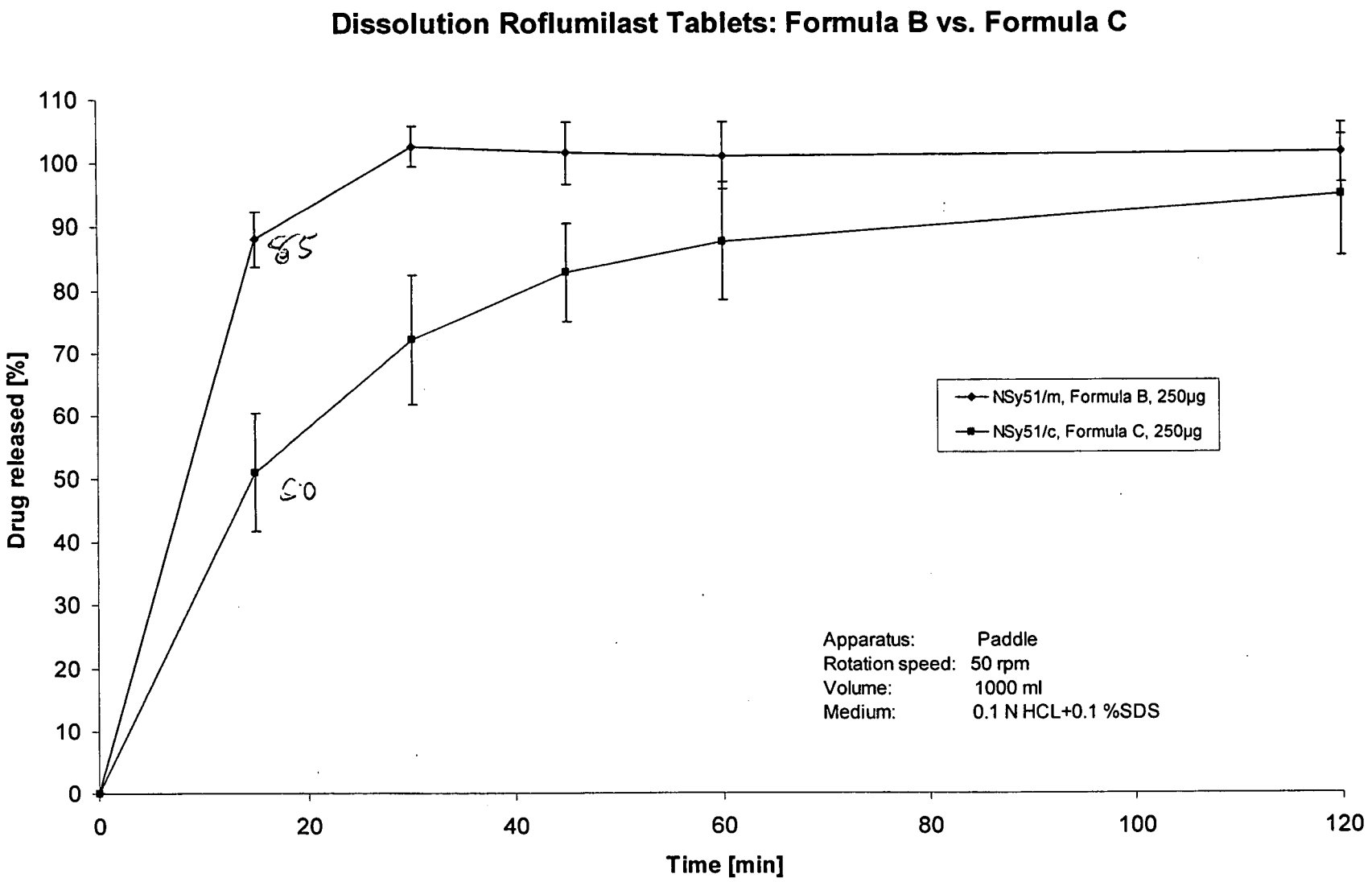
50 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
Time [min]
0
10
20
30
40
50
60
70
80
90
100
110
120
0
20
40
60
80
100
120
NSy51/g, Formula B, 50µg
NSy51/a, Formula C, 50µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 500 ml
Medium: 0.1 N HCL+0.1 %SDS

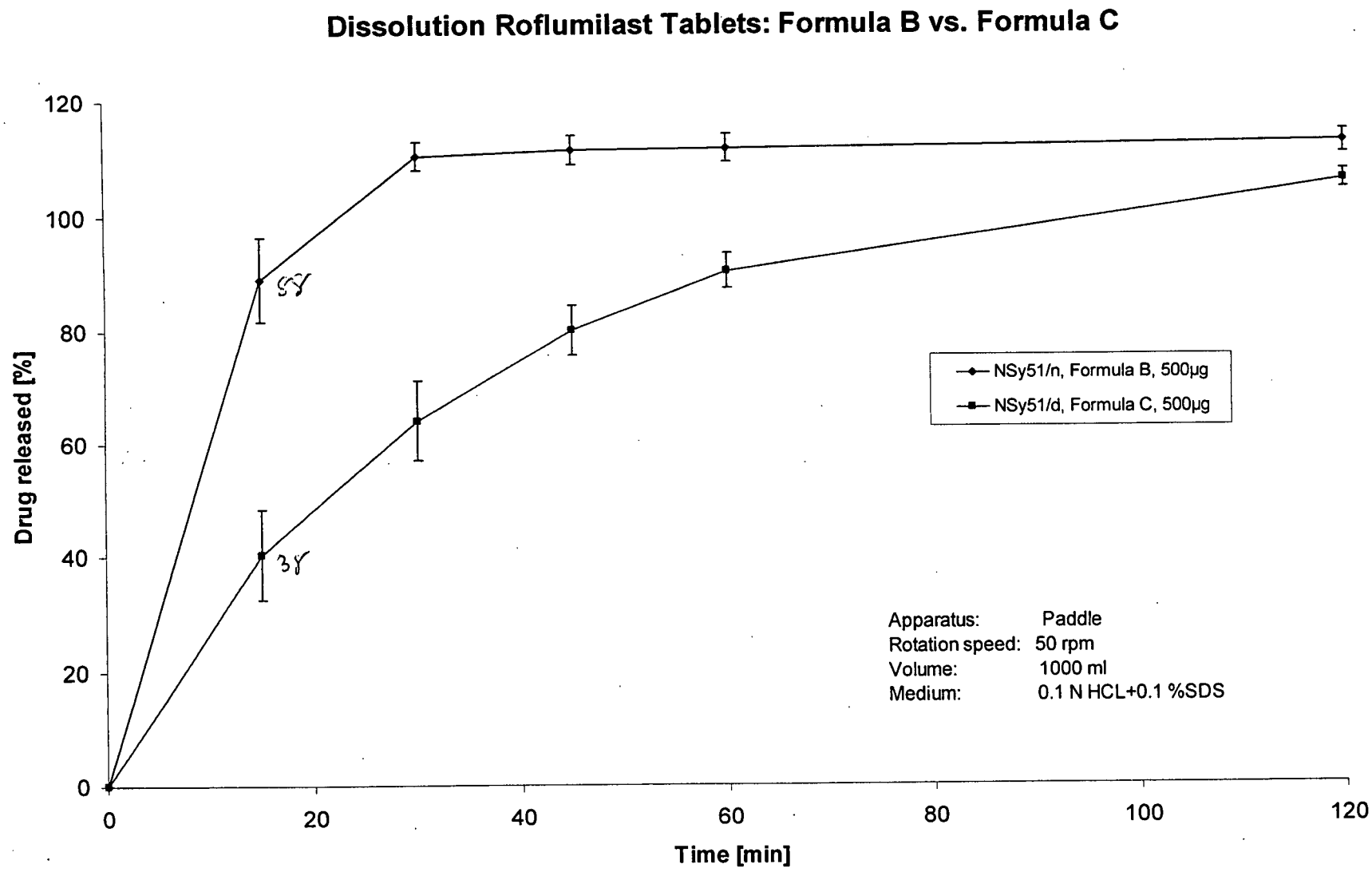
125 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
110
100
90
80
70
60
50
40
30
20
10
0
0
20
40
60
80
100
120
Time [min]
82
55
NSy51/k, Formula B, 125µg
NSy51/b, Formula C, 125µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 1000 ml
Medium: 0.1 N HCL+0.1 %SDS

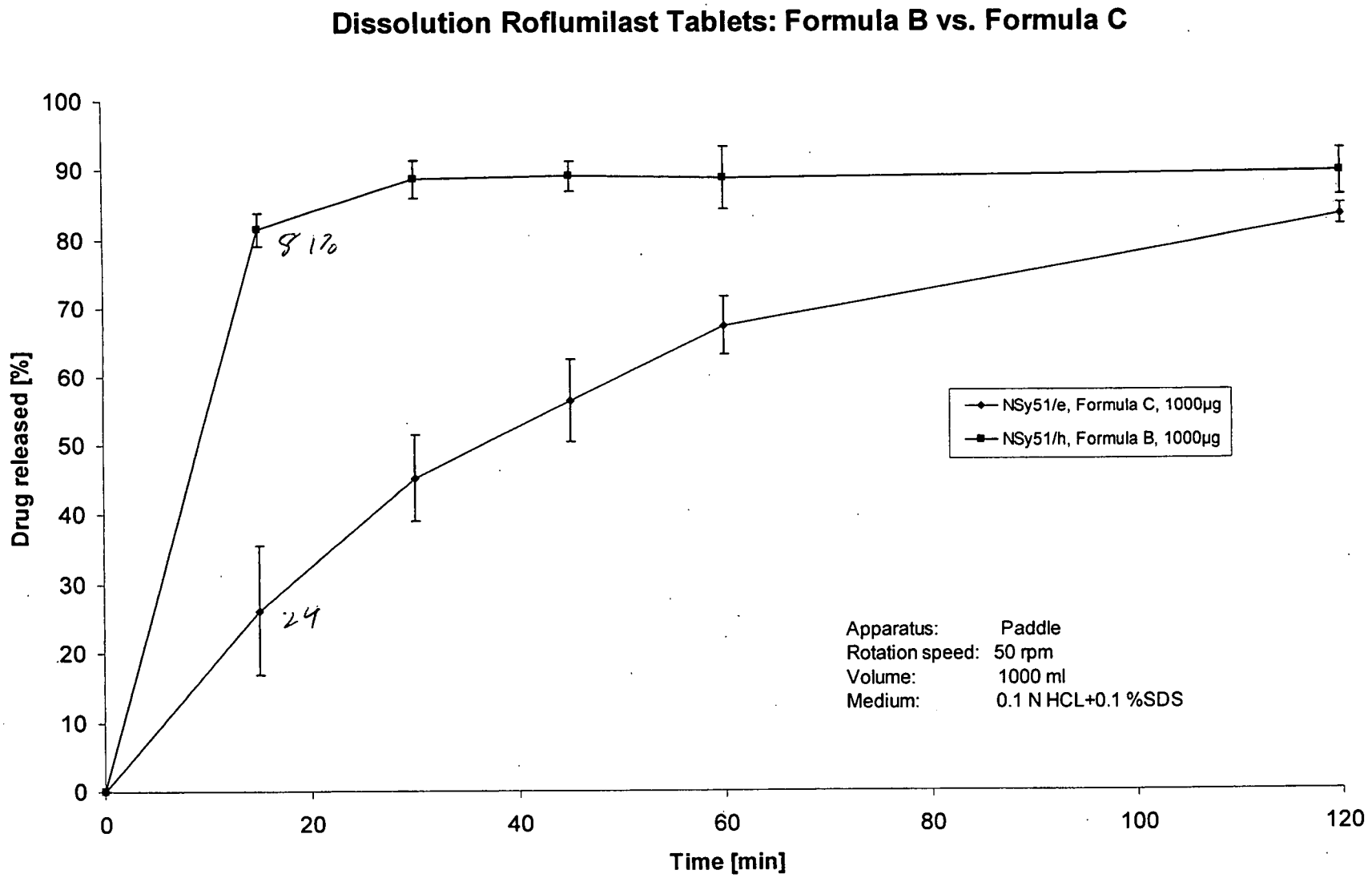
250 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
Time [min]
0
10
20
30
40
50
60
70
80
90
100
110
0
20
40
60
80
100
120
NSy51/m, Formula B, 250µg
NSy51/c, Formula C, 250µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 1000 ml
Medium: 0.1 N HCL+0.1 %SDS

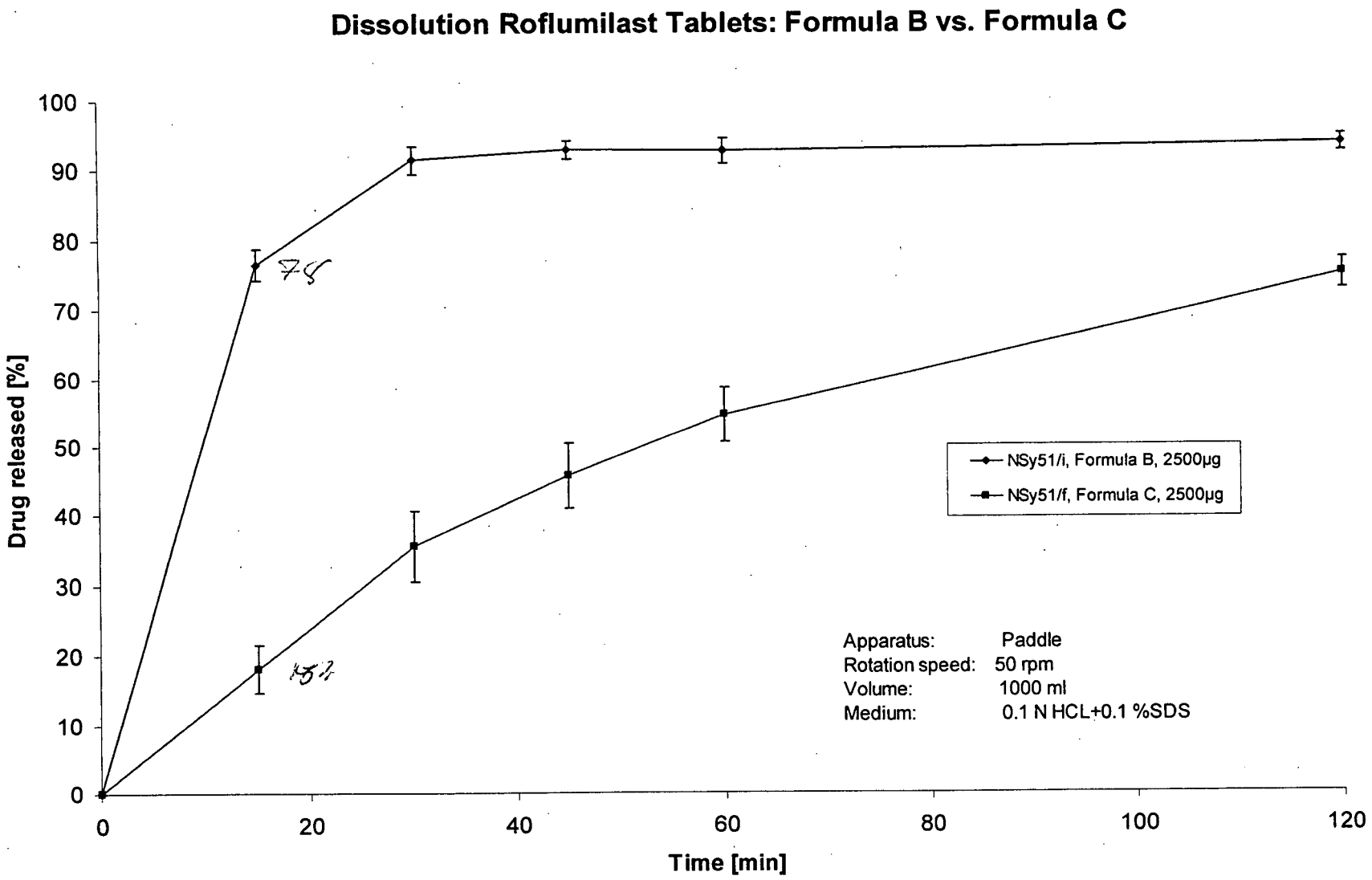
500 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
Time [min]
0
20
40
60
80
100
120
NSy51/n, Formula B, 500µg
NSy51/d, Formula C, 500µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 1000 ml
Medium: 0.1 N HCL+0.1 %SDS

1000 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
Time [min]
100
90
80
70
60
50
40
30
20
10
0
0
20
40
60
80
100
120
8 1%
24
NSy51/e, Formula C, 1000µg
NSy51/h, Formula B, 1000µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 1000 ml
Medium: 0.1 N HCL+0.1 %SDS

2500 µg


Dissolution Roflumilast Tablets: Formula B vs. Formula C
Drug released [%]
Time [min]
0
10
20
30
40
50
60
70
80
90
100
0
20
40
60
80
100
120
NSy51/i, Formula B, 2500µg
NSy51/f, Formula C, 2500µg
Apparatus: Paddle
Rotation speed: 50 rpm
Volume: 1000 ml
Medium: 0.1 N HCL+0.1 %SDS